

To: Griffith Hack GPO Box 4164 SYDNEY NSW 2001		Rec'd PCT/PTQ JUN 2005 10/538303 (PCT Rule 71.1) NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT Date of mailing day/month/year 3-1 MAR 2005	
Applicant's or agent's file reference FP18908 / TJS		IMPORTANT NOTIFICATION	
International Application No. PCT/AU2003/001626	International Filing Date 9 December 2003	Priority Date 9 December 2002	
Applicant DUNLOP, Colin			

1.	The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2.	A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3.	Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.
4.	REMINDER The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301). Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned. For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP18908	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/001626	International Filing Date (day/month/year) 9 December 2003	Priority Date (day/month/year) 9 December 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61F 7/00, 7/02, 7/03, 7/08		
Applicant DUNLOP, Colin		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.																								
2.	This REPORT consists of a total of 4 sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 12 sheet(s).																								
3.	This report contains indications relating to the following items: <table style="width: 100%; border: none;"> <tr> <td style="width: 5%;">I</td> <td style="width: 5%;"><input checked="" type="checkbox"/></td> <td>Basis of the report</td> </tr> <tr> <td>II</td> <td><input type="checkbox"/></td> <td>Priority</td> </tr> <tr> <td>III</td> <td><input type="checkbox"/></td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>IV</td> <td><input checked="" type="checkbox"/></td> <td>Lack of unity of invention</td> </tr> <tr> <td>V</td> <td><input checked="" type="checkbox"/></td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>VI</td> <td><input type="checkbox"/></td> <td>Certain documents cited</td> </tr> <tr> <td>VII</td> <td><input type="checkbox"/></td> <td>Certain defects in the international application</td> </tr> <tr> <td>VIII</td> <td><input type="checkbox"/></td> <td>Certain observations on the international application</td> </tr> </table>	I	<input checked="" type="checkbox"/>	Basis of the report	II	<input type="checkbox"/>	Priority	III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	IV	<input checked="" type="checkbox"/>	Lack of unity of invention	V	<input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	VI	<input type="checkbox"/>	Certain documents cited	VII	<input type="checkbox"/>	Certain defects in the international application	VIII	<input type="checkbox"/>	Certain observations on the international application
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Date of submission of the demand 8 July 2004	Date of completion of the report 16 March 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer SARAVANAMUTHU PONNAMPALAM Telephone No. (02) 6283 2070

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description, pages , as originally filed,
pages , filed with the demand,
pages 1-9 , received on 9 March 2005 with the letter of 9 March 2005
- ☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages 10-12, received on 9 March 2005 with the letter of 9 March 2005
- ☒ the drawings, pages 1,2 , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Preliminary Examining Authority has found that there are different inventions as follows:

1. Claims 1-7 and 13 & 14 are directed to a surgical warming blanket comprising at least two layers capable of forming an air space between them. It is considered that allowing access to the patient's body for surgery without disturbing the blanket comprises a first "special technical feature".
2. Claims 8-12 are directed to a heating unit for a patient warming system. It is considered that the provision of a feedback means for determining whether a patient warming blanket is attached, and responsive to a determination that the blanket is not attached to disable the delivery of warmed air to the blanket, comprises a second "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

Because no additional search fees were paid, the International Search Report of the International Searching Authority was restricted to the invention claimed in claims 1-7 and 13 & 14. Consequently, the International Preliminary Examination must be likewise restricted, without the need to issue an invitation to so restrict it.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☐ the parts relating to claims Nos. 1-7 and 13 & 14

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-7, 13.& 14	YES
	Claims	NO
Inventive step (IS)	Claims 1-7, 13 & 14	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-7, 13 & 14	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

NOVELTY (N) and INVENTIVE STEP (IS)

A. The documents constituting the closest prior art are:

- (i) US 5304213 A
- (ii) US 5928274 A

B. The subject matter of claims 1 & 13 differs from these prior art documents in that it is arranged to keep the patient warm without covering them.

C. The distinguishing features of the invention will enable access to the patient body for surgery without disturbing the blanket.

D. Therefore the application satisfies the criteria set forth in PCT Article 33(2-3), concerning the novelty and inventive step of the independent claims 1 & 13.

E. The criteria concerning novelty and inventive step of claims 2-12 & 14 are satisfied because these claims are dependent on claim 1.

INDUSTRIAL APPLICABILITY (IA)

The invention defined in claims 1-7, 13 & 14 satisfies the criterion set forth in PCT Article 33(4).

PATIENT WARMING SYSTEM

Field of the Invention

5 The present invention relates to a warming system for patient care and, particularly, but not exclusively, to a warming system for use in veterinary care.

Background of the Invention

10

 There are many circumstances in human and animal medicine where it is necessary to keep a patient warm to, for example, prevent or treat hypothermia.

 In human medicine, it is known to provide patient
15 warming systems which include a patient warming blanket and a heating unit. The patient warming blanket includes two layers which are bonded or stitched together at a seam and are otherwise separable from each other to form a hollow space within the blanket when warm air is pumped
20 from the heating unit via a delivery tube in between the two layers. One of the layers contains a plurality of air holes which allow the pumped warm air to escape from the blanket. In operation, the patient is wrapped or covered in the warming blanket with the layer with the holes next
25 to the patient. Warm air is pumped in from the heating unit and escapes from the air holes on the inside layer of the blanket and keeps the patient warm.

 These patient warming systems are designed for use in human medicine only, for the prevention and treatment of
30 hypothermia during anaesthesia and critical care.

 There is, however, a similar need for a patient warming system in veterinary care. Presently, similar warming systems are used as those designed for human

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patients. There are a number of problems associated with the use of the human patient warming system in veterinary care, however.

Small animals have a relatively large surface area to volume ratio, which makes them particularly susceptible to hypothermia. The applicants have found that using a conventional human warming system to maintain the body temperature of a relatively small animal can actually result in cooling of the animal (which can lead to death). This occurs, we believe, because the air flow is delivered to the patient by individual, discreet holes in the inner layer of the warming blanket. In a patient with relatively large surface area to volume, delivery of air from an air hole, so that the air is moving relatively rapidly, can cause the patient to chill, as the air takes away more heat from the surface of the patient than it delivers. Obviously, this is very dangerous in a critical care situation.

Another problem is that the heating unit used in the human systems typically only heats to a temperature of 43°C. Animals have a range of body temperatures and in many circumstances a system which provides heated air at a maximum of 43°C is not sufficient.

Another problem which relates to animals, which in veterinary situations are often smaller and sometimes much smaller than human beings, is that the human patient warming blankets are relatively large, and a small animal placed under one of these will not be adjacent sufficient air holes to provide sufficient warm air to maintain the animal's temperature.

Further, in surgery and other circumstances where sterile conditions are required, having air blown at relatively high velocity through a small hole can result

in contamination of the site eg. the surgical site, via substances blown onto the surgical site by air from the air holes.

5 Summary of the Invention

In accordance with a first aspect, the present invention provides a surgical warming blanket arranged for use during surgery on a patient and comprising at least
10 two layers capable of forming a hollow air space between them for receiving warmed air from a heating unit, the two layers and air space being arranged in operation to form a substantially tubular arrangement at least partially surrounding a patient receiving space, whereby when warm
15 air is passed into the air space it is delivered to the patient receiving space via the blanket, to maintain warm air within the patient receiving space, the patient receiving space receiving the patients body and allowing access to the patients body for surgery without disturbing
20 the blanket.

In one embodiment, at least one of the two layers has a proportion of its surface formed of porous material so that warmed air may escape via the porous material into the patient receiving space.

25 The pervious material is adjacent to, in use, a patient receiving treatment. Delivering heat spread over the surface of the porous material advantageously has the effect of evenly warming the patient without forming relatively high velocity streams of air (as in the prior
30 art blanket where the air is delivered via discreet holes). Animals, therefore, and in particular small animals, are not at risk of being cooled by relatively high velocity air streams. In one embodiment, a

substantial proportion of the surface of the one layer is of porous material. Preferably, a majority of the surface of the one layer is of porous material. In operation, warm area is advantageously delivered at relatively low velocity over the proportion of the surface of the one layer.

Preferably, the blanket is designed not to cover the animal patient, but instead to provide a patient receiving area in which the patient lies surrounded at least on three sides by a tube formed by the blanket when air is pumped into the air space. In this embodiment, at least the sides of the tube facing inwards towards the patient are of the porous material. This has the effect of passing warm air over the patient within the space, so no matter how large the patient, the air in the space will be kept at substantially the same temperature.

Preferably, the surface of the blanket is fluid repellent, so that any liquid contamination rolls off the blanket.

In an alternative embodiment, the entire blanket may be made of porous material so that warmed air is delivered over the entire surface of the blanket that is exposed. The unexposed surface of the blanket e.g. facing down on a bench, may not deliver air. The exposed surface, however, including the surface which may be adjacent to patient in operation, will deliver air. This saves cost in manufacture of the blanket as it is only necessary to manufacture the blanket from one type of material. This can be significant, as in the majority of cases these blankets are intended to be disposable after one use.

One other problem with the conventional human patient warming systems is that it has been known for carers to direct heat directly from the heating unit via a delivery

tube directly onto the patient. This can cause burning, particularly in small animals, and is not something that should occur.

In accordance with a third aspect, the present invention provides a heating unit for a patient warming system, the heating unit including a delivery port for delivering warmed air to a patient warming blanket, and a feedback means for determining whether a patient warming blanket is attached and being responsive to a determination that the patient warming blanket is not attached, to disable delivery of warmed air via the port.

Preferably, the feedback means comprises a pressure sensor, for sensing back pressure on the air delivery port. When a blanket is attached, there will be a certain amount of back pressure on the delivery port, so that when this back pressure is detected, air may delivered.

Preferably, the heating unit is arranged to heat air to a range of temperatures, preferably up to 46°C.

In accordance with a fourth aspect, there is provided a heating system comprising a patient warming blanket in accordance with the first aspect of the present invention and a heating unit in accordance with the third aspect of the present invention.

In accordance with a fifth aspect, the present invention provides a method of warming a patient during surgery, comprising the steps of receiving the patient within a patient receiving space within which the patients body is accessible for surgery, and passing warmed air into the patient receiving space to keep the patient warm.

30

Brief Description of the Drawings

Figure 1 is a plan view of a patient warming blanket.

in accordance with one embodiment of the present invention, shown connected to a heating unit in accordance with one embodiment of the present invention;

Figure 2 is a cross sectional view on line XX of
5 Figure 1;

Figure 3 is a plan view of a patient warming blanket in accordance with a further embodiment of the present invention; and

Figure 4 is a view from the front of the embodiment
10 of Figure 3.

Description of Preferred Embodiment

With reference to the figures, a patient warming
15 system in accordance with an embodiment of the present invention is illustrated, particularly being designed for use in veterinary medicine. The patient warming system comprises a heating unit 1 (to be described in more detail later) and a patient warming blanket 2.

20 The patient warming blanket 2 includes first 3 and second 4 layers of material which form a hollow air space 5 between them. In this embodiment, when the warming blanket 2 is not being used, it will lie substantially flat as no air is being pumped into the air space 5. In
25 use, however, when air is being pumped into the air space 5, the blanket "inflates" to give the profile shown in the cross-section of Figure 2.

The first layer 3 is substantially non porous to air. The second layer 4, however, is made of porous material
30 and is substantially porous over its entire surface area. Warm air pumped into the hollow air space 5, therefore, escapes via the entire surface of the second layer 4.

The warming blanket 2 may be made of any appropriate

material and in this embodiment is made from polyester.
The second surface 4 being of porous polyester.

The arrangement of the first 3 and second layers 4
in operation in this embodiment forms a tubular
5 arrangement which extends about three sides of a patient
receiving space 6. In this embodiment, a continuation 7
of the first layer 3 provides a blanket base on which the
patient may lie.

In operation, warmed air is provided from the heating
10 unit 1 via a flexible heat delivery tube 8 into a port 9
to the interior space 5 of the blanket. The warmed air
inflates the blanket to give the profile illustrated in
Figure 2. The patient is positioned within the patient
receiving space 6. Warm air escapes via the porous second
15 layer 4 into the patient receiving space maintaining the
patient receiving space 6 at a substantially even
temperature. The shape of the blanket maximises the
convective surface area for heating.

The material of the warming blanket 2 is treated to
20 be fluid repellent, so that any liquid contamination rolls
off the blanket.

In an alternative embodiment, the blanket may consist
of the same main material over all of its surface. Warmed
air is therefore delivered over all of the exposed surface
25 of the blanket. This blanket may be cheaper to make.

The heating unit 1 includes a feedback means which in
this embodiment is a pressure sensor. The pressure sensor
is arranged to sense a certain amount of back pressure on
a delivery port 10 of the heating unit which delivers
30 warmed air to the delivery tube 8. The existence of this
back pressure implies that a warming blanket 2 is attached
to the delivery tube 8. If the back pressure signal is
not received by the pressure sensor, then delivery of

warmed air 10 via the port is disabled. This prevents any operative attempting to provide warmed air directly to a patient via the delivery tube 8, without using a warming blanket.

5 The heating unit 1 includes control and selection means 12, 13, 14 that enables a selection of plurality of temperatures for the warmed air, and in this embodiment warmed air can be delivered at temperatures of 34, 37, 40, 43 or 46 degrees Centigrade.

10 The heating unit 1 is based on a conventional heating unit, but adapted to deliver the above temperatures. A further adaptation is the addition of the pressure sensor and feedback to temperature control circuitry (not shown) to switch off the delivery of warmed air if a back
15 pressure is not sensed (implying that the warming blanket 2 is not attached to the delivery tube 8).

 Figure 3 and Figure 4 show an alternative embodiment of the patient warming blanket. The alternative patient warming blanket 20 comprises an air inlet 21 which is on
20 one "leg" 22 of the blanket. Otherwise, the blanket is of similar construction to the patient warming blanket of Figures 1 and 2. Similar reference numerals have been used for similar components as the embodiment of Figures 1 and 2.

25 In the above-described embodiment the patient warming blanket will be appropriately dimensioned for veterinary care. Example dimensions include 560mm width, 1110mm length, with width of each of the arms when inflated being 110mm. Note that these dimensions are examples only and,
30 the present invention is not limited to these dimensions.

 While the above description refers to application of the warming system with animal patients, the system of the present invention is not limited to use with animal

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patients and can be used with human patients eg. small human patients.

Modifications and variations as would be apparent to a skilled addressee are deemed to be within the scope of
5 the present invention.

CLAIMS

1. A surgical warming blanket arranged for use during surgery on a patient and comprising at least two layers
5 capable of forming a hollow air space between them for receiving warmed air from a heating unit, the two layers and air space being arranged in operation to form a substantially tubular arrangement at least partially surrounding a patient receiving space, whereby when warm
10 air is passed into the air space it is delivered to the patient receiving space via the blanket, to maintain warm air within the patient receiving space, the patient receiving space receiving the patients body and allowing access to the patients body for surgery without disturbing
15 the blanket.
2. A surgical warming blanket in accordance with Claim 1, wherein the tubular arrangement surrounds the patient receiving space on three sides.
20
3. A surgical warming blanket in accordance with Claim 1 or Claim 2, wherein one of the two layers of the blanket has a portion of its surface formed of pervious material so that the warmed air is delivered to the patient
25 receiving space via the pervious material.
4. A surgical warming blanket in accordance with Claims 1, 2 or 3, wherein the surface of the blanket is arranged to be fluid repellent, so that liquid
30 contamination is repelled.
5. A surgical warming blanket in accordance with any one of the preceding claims, being sized and shaped so that

the patient receiving space is arranged to receive an animal.

6. A surgical warming blanket in accordance with
5 Claim 5, wherein the blanket is shaped and sized so that
the patient receiving space is arranged to receive a large
animal, such as a large dog.

7. A surgical warming blanket in accordance with any one
10 of Claims 1 to 4, the blanket being sized and shaped so
that the patient receiving space can receive a human
adult.

8. A heating unit for a patient warming system, the
15 heating unit including a delivery port for delivering
warmed air to a patient warming blanket, and a feedback
means for determining whether a patient warming blanket is
attached and responsive to a determination that the
patient warming blanket is not attached, to disable
20 delivery of warmed air via the port.

9. A heating unit in accordance with Claim 8, wherein
the feedback means includes a pressure sensor for sensing
back pressure on the air delivery port.

25

10. A heating unit in accordance with Claims 8 or 9, the
heating unit being arranged to heat the air to a range of
temperatures.

30 11. A heating unit in accordance with Claim 10, being
arranged to heat air up to 46°C.

12. A heating system comprising a patient warming blanket

in accordance with any one of the Claims 1 to 7 and a heating unit in accordance with any one of Claims 8 to 11.

13. A method of warming a patient during surgery,
5 comprising the steps of receiving the patient within a patient receiving space within which the patients body is accessible for surgery, and passing warmed air into the patient receiving space to keep the patient warm.
- 10 14. A method in accordance with Claim 13, wherein a surgical warming blanket in accordance with any one of Claims 1 to 8 is utilised to form the patient receiving space and deliver the warmed air thereto.